

## **REMARKS**

Claims 1, 2, 24, and 45 have been amended to recite the limitation “wherein the hypertonic, high salt reagent comprises salt in an amount effective to precipitate proteins out of the lysate.” Support for this claim language can be found in originally filed claims 9, 30, and 51, and paragraph [0013]. Claims 10-12, 31-33 and 52-54 have been amended to correct dependencies. Accordingly, no new matter has been added. Claims 9, 30 and 51 are currently canceled. Claims 8, 18, 29, 39, 50 and 60 were previously canceled. Claims 1-7, 10-17, 19-28, 31-38, 40-49, and 52-59, and 61-65 remain pending in the instant application.

## **REQUEST FOR IN-PERSON/TELEPHONIC INTERVIEW BEFORE ISSUANCE OF OFFICE ACTION**

Applicants herein request an in-person interview with the Examiner and her supervisor before an office action is issued in the application. Some of the participants may not be able to attend an in-person interview as they reside out of the country, and hence the request is for both an in-person/telephonic interview.

## **REQUEST FOR RCE**

Applicants are filing herewith an RCE and thus request entry of the present claim amendments.

## **ARGUMENT**

Claims 1-7, 9-16, 19-28, 30-37, 40-49, and 51-58, and 61-65 have been rejected under 35 U.S.C. 103 (a) over Fairman (2002/0068280) and claims 17, 38 and 59 have been rejected under 35 U.S.C. 103 (a) over Fairman and Hanak (U.S. Patent 6,780,632). Applicants respectfully submit that the present claim amendments have rendered the above rejections moot and request withdrawal of these claim rejections. The independent claims have been amended to the limitation: “wherein the hypertonic, high salt reagent comprises salt in an amount effective to precipitate proteins out of the lysate” and as such all the dependent claims also require such limitation. With this amendment, it is clear that the suspension solution in which the biological material is suspended (before lysis) is a hypertonic, high salt reagent that comprises a salt in an amount that is effective to precipitate proteins out of the lysate. Since the claims require the

steps in the claim be followed sequentially, it is clear that the solution that suspends the biological material is the hypertonic solution that contains the salt in the amount effective to precipitate the proteins out of the lysate. It is not the lysis solution but the suspension solution that is a hypertonic, high salt solution. Neither of the cited references teach nor suggest this limitation nor the sequential steps also required by the claims.

Hanak does not teach or suggest a cell suspension solution that is a “hypertonic, high salt reagent comprises salt in an amount effective to precipitate proteins out of the lysate.” First, as opposed to only two solutions required by the present invention (a suspension solution which is hypertonic, high salt and a cell lysis solution), Hanak requires four solutions. See paragraph [0010] describing four solutions -- after application of the first two solutions, a third solution lyses the cells and a fourth solution precipitates the proteins. Thus, not only does Hanak’s system require four solutions, in his method the cells are first lysed and then the mixture is exposed to another different solution that precipitates the proteins. Accordingly, Hanak does not teach or suggest the claimed sequential steps of first suspending the cells in a hypertonic, high salt reagent that is able to precipitate proteins out of the lysate after exposing the cell suspension to a lysis solution. In fact, in paragraph [0031] Hanak suggests that the in some situations, it may be preferable to use certain detergents in the lysis solution to avoid protein aggregation: “Alternatively, zwitterionic detergents like CHAPS and N-Dodecyl-N,N-dimethyl-3-ammonio-1-propane sulfonate may be useful where protein aggregation is to be avoided.” Thus it appears that Hanak may be desirous of not having the proteins precipitate out in the lysate but rather, wishes to postpone this step until a fourth solution is added in which to cause protein precipitation. Hanak states further in paragraph [0035] that “it is contemplated that addition of the fourth aqueous solution will result in substantially complete precipitation of the proteins present in the extraction mixture.” Thus, it is clear that Hanak is not only teaching four solutions, but also teaches that lysis is to occur first and then a different solution is added to precipitate the proteins. This is clearly not the sequential steps or the solutions of the claimed invention: first a hypertonic, high salt solution and then a lysis solution.

Not only does Hanak require four solutions as opposed to the present claims only requiring two solutions for DNA isolation, Hanak’s order of adding the solutions is different and there is no suggestion to alter his order (especially as discussed above, Hanak provides guidance in how to keep protein precipitation/aggregation in abeyance until after the lysis step has

occurred). Applicants would like to remind the Examiner that the deletion of a step from a prior art method can be patentable, *see In re Walter*, 102 F.2d 855, 857 (C.C.P.A. 1938) (“a method is not necessarily anticipated by various disclosures of the separate elements or steps of the method. . . . This is true where invention rests in combining the steps in such an unobvious sequence or order as to produce new and useful results.”)(emphasis added). Thus, the fact that the present invention requires a sequential ordering of two solutions as opposed to the Hanak’s four solutions in a different order is a patentable and is an unobvious difference as the present claimed invention also produces new and useful results as mentioned in the specification and in previous responses (i.e. employs fewer steps than conventional methods, which lessens the risk of contamination and provides quicker results - see paragraph[0005]).

Fairman also does not teach or suggest “wherein the hypertonic, high salt reagent comprises salt in an amount effective to precipitate proteins out of the lysate.” On col. 11, the Fairman discusses cell lysis and plasmid recovery. The method employed by Fairman teaches “the standard alkaline method” of lysing bacteria. This method uses first an alkaline solution to lyse the cells. Thereafter a solution is added to precipitate cellular debris. Thus, there is no teaching or suggestion of the claimed method that requires the sequential steps or the solutions of the claimed invention: first a hypertonic, high salt solution and then a lysis solution.

Since neither of the cited references teach or suggest all of the elements of the claimed invention, applicants respectfully request withdrawal of the grounds of rejection and request allowance of the claims.

## CONCLUSION

If any additional fees are required, they maybe charged to Deposit Account No: 50-4254.

Respectfully Submitted,

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Teresa A. Lavenue  
Registration No; 47,737

Baker, Donelson, Bearman, Caldwell & Berkowitz, PC  
555 11<sup>th</sup> Street, NW  
Washington, DC 20004  
Direct Phone: (202) 508-3451